UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*, *ex rel.* ZACHARY SILBERSHER, **Plaintiffs,** **v.** **JANSSEN BIOTECH, INC., *et al.*,** **Defendants.**	**Case No. 19–cv–12107–KM–ESK** **OPINION AND ORDER**

KIEL, U.S.M.J.

THIS MATTER having come before the Court on the motions of plaintiff-relator Zachary Silbersher in this *qui tam* case (Qui Tam Case) brought under the False Claims Act, 31 U.S.C. §§3729–3733, to: (1) compel the production by defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, and Johnson & Johnson (collectively, Janssen) of sealed documents (Sealed Documents) from an abbreviated new drug application case (ANDA Case) concerning the pharmaceutical product Zytiga (Motion To Compel) (ECF No. 198), and (2) amend the discovery confidentiality order (ANDA DCO) entered in the ANDA Case to allow for the production of the Sealed Documents to Silbersher by Janssen (Motion To Amend) (ECF No. 199); and Janssen having filed partial opposition to the Motion To Compel and Motion To Amend (ECF Nos. 219, 220); and two sets of nonparties — Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, Mylan), and Apotex Corp. and Apotex Inc. (collectively, Apotex) — which were generic manufacturers named by Janssen as defendants in the ANDA Case, having jointly opposed the Motion To Compel and Motion To Amend (ECF Nos. 216, 217, 218); and Silbersher having filed reply briefs (ECF Nos. 221, 222); and the Court finding:

1. Janssen's original patent for the prostate-cancer drug abiraterone acetate (the '213 patent), which is marketed in tablet form under the brand name Zytiga, was set to expire in 2016. (ECF No. 63 p.6.) Silbersher alleges that Janssen fraudulently obtained a new patent for Zytiga in 2014 (the '438 patent) to block the entry of lower-priced generic competitors into the market when the '213 patent expired. (*Id.* p.11.) Nevertheless, several generic manufacturers filed abbreviated new drug applications with the United States Food and Drug

Administration (FDA) for approval to produce and sell abiraterone acetate tablets in anticipation of the expiration of the '213 patent, including Mylan and Apotex in April 2015. (ECF No. 218-2 p.2; ECF No. 218-3 p.2.)

2. Janssen brought the ANDA Case in the District of New Jersey against the generic manufacturers in 2015 for allegedly infringing the '438 patent. *See BTG Int'l Ltd. v. Amneal Pharms. LLC*, Case No. 15-05909. Soon thereafter, several generic manufacturers instituted *inter partes* review proceedings (IPR Proceedings) before the United States Patent Trial and Appeal Board (PTAB) to challenge the issuance of the '438 patent, including Mylan. (ECF No. 216 pp.5, 6.) The ANDA Case and IPR Proceedings were ultimately resolved in a consolidated appeal in May 2019 by the United States Court of Appeals for the Federal Circuit, which found the '438 patent to be invalid on the basis of obviousness due to the prior art presented by, among other sources, the '213 patent. *See BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063, 1073–77 (Fed.Cir. 2019). Before the ANDA Case and IPR Proceedings were resolved in the Federal Circuit, Mylan's application and Apotex's application to market and sell generic abiraterone acetate tablets were both approved by the FDA on October 31, 2018. (ECF No. 218-1 p.2 ¶¶2, 3.)

3. During the course of the ANDA Case, Magistrate Judge James B. Clark issued the ANDA DCO in March 2016. *See* Case No. 15-05909, ECF No. 172. The ANDA DCO prevented disclosure to nonparties of any Sealed Documents deemed by either Janssen or the generic manufacturers to contain confidential information. *Id.* ¶¶3, 5.

4. This Qui Tam Case was initially brought against Janssen in the Northern District of California in 2017, and then transferred to this Court in 2019. (ECF Nos. 1, 52.) This Qui Tam Case does not name the generic manufacturers as either defendants or interested parties. Silbersher alleges that by extending its patent-based monopoly, Janssen fraudulently inflated the cost of abiraterone acetate tablets, thereby causing Medicare and other federal and state government health programs to pay inflated prices to Janssen to cover Zytiga's full cost at taxpayer expense for those insured by the government health programs. (*See generally* ECF No. 63; *see also* ECF No. 198-1 p.4.)

5. Silbersher sought to ascertain when the generic manufacturers would have been ready to enter the market for abiraterone acetate tablets, and the extent to which Janssen's conduct and the concomitant 30-month stay in the ANDA Case squelched that readiness. Thus, Silbersher requested that Janssen produce the following Sealed Documents that were protected from disclosure by the ANDA DCO, including Sealed Documents produced by the generic manufacturers to Janssen during the ANDA Case:

> (a) docket filings; (b) expert reports; (c) transcripts of court proceedings and depositions (with their exhibits); (d) interrogatories, requests for admissions, and document requests; (e) responses and answers to interrogatories, requests for admissions, and document requests; (f) documents relating to mediation efforts; and (g) logs, lists, indices, or other documents or databases identifying documents produced, obtained through, or withheld from discovery by the parties.

(ECF No. 198-1 p.8.)

6. Janssen notified the generic manufacturers of Silbersher's requests. Mylan and Apotex objected to Janssen's production of Sealed Documents that pertained to them. (*Id.* p.6 n.2.) No other generic manufacturer objected in full. Silbersher now moves to have the ANDA DCO amended so that he can be included among those permitted to have access to the Sealed Documents produced in the ANDA Case, and to compel Janssen to produce those Sealed Documents in its possession over the objections of Mylan and Apotex. (ECF Nos. 198-1, 199-1.)

7. In support of the Motion To Amend and Motion To Compel, Silbersher argues that the Qui Tam Case involves an issue of great importance, *i.e.*, Janssen's alleged fraudulent scheme to overcharge government health programs by hundreds of millions of dollars for Zytiga, and that the Sealed Documents may help to further reveal the extent of that fraud. (ECF No. 198-1 p.8.) In addition, Silbersher argues that Janssen is a "well-resourced drug compan[y] with ready access to the requested information from the ANDA [Case] — specifically, documents containing or implicating the non-consenting generic companies' confidential information — while [Silbersher] does not." (*Id.*) Thus, Silbersher minimizes the burden on Janssen and, in effect, the generic manufacturers for Janssen to produce the Sealed Documents. (*Id.* pp.9, 10.) Silbersher also argues that he will abide by the terms of the ANDA DCO, and that he "is not involved in the sale or manufacture of pharmaceutical products, and his … access to [Sealed] [D]ocuments will not result in any potential competitive injury to the generic [manufacturers]." (*Id.* p.10; *see* ECF No. 199-1 p.9.)

8. In opposing the Motion To Amend and Motion To Compel, Mylan and Apotex argue that they relied upon the ANDA DCO when revealing their sensitive proprietary information in the ANDA Case, and that they cannot be expected to simply forgo their rights under the ANDA DCO now because it is convenient for Silbersher. (ECF No. 216 p.1; ECF No. 218 p.4.) They reiterate that "[s]uch information is central to Mylan's and Apotex's business and drug

development operations and, therefore, their positions in the competitive marketplace," and that they legitimately fear such disclosure may lead to "competitive injur[ies]" even if Silbersher is not in the business of producing generic pharmaceuticals. (ECF No. 218 p.13; ECF No. 216 p.14). Along those lines, Mylan and Apotex point out that they expected their Sealed Documents to be destroyed by Janssen under the terms of the ANDA DCO itself. *See* Case No. 15-05909, ECF No. 172 p.19 (providing that "[e]ach receiving party shall, within ninety (90) days of final termination of [the ANDA Case] (including all appeals), either return to the producing party or destroy all of the producing party's Protected Information in the receiving party's possession").

9. Mylan and Apotex argue further that most of the information that Silbersher seeks concerning Mylan and Apotex is publicly available under the dockets for the ANDA Case, the IPR Proceedings, the PTAB, and the Federal Circuit. (ECF No. 216 pp.9, 10.) Mylan and Apotex assert that their readiness to produce and market generic abiraterone acetate tablets is apparent and a matter of public record, given the ANDA applications they filed with the FDA in 2015, and that they could not go to market until the FDA approved their applications in any event. (*Id.* pp.4, 11.) They point out that the existence of the '438 patent did not delay the FDA's approval of an application to produce abiraterone acetate tablets by another generic manufacturer in October 2017, *i.e.*, Wockhardt Bio AG. (*Id.* p.11; ECF No. 216-1 p.2.) Finally, Mylan and Apotex argue that their Sealed Documents, including their financial forecasts, will provide no enlightenment as to Janssen's intent in prosecuting the '438 patent. (ECF No. 216 pp.4, 9, 10, 12.)

10. In deciding whether to modify the ANDA DCO, I must consider whether: (a) the disclosure of the Sealed Documents would violate any privacy interests; (b) the information is being sought for a legitimate or an improper purpose; (c) the disclosure of the Sealed Documents will cause a party embarrassment; (d) confidentiality is being sought over information that is important to public health and safety; (e) the sharing of information among litigants will promote fairness and efficiency; (f) a party benefitting from the ANDA DCO is a public entity or official; (g) the Qui Tam Case involves issues important to the public; and (h) the parties in the ANDA Case relied on the ANDA DCO. *See Medeva Pharma Suisse A.G. v. Roxane Labs., Inc.*, No. 07-05165, 2011 WL 3841377, at *2 (D.N.J. Aug. 26, 2011) (citing *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 790 (3d Cir. 1994)). These factors are neither exhaustive nor mandatory, and I have the discretion to evaluate the competing considerations presented here. *See Glenmede Tr. Co. v. Thompson*, 56 F.3d 476, 483 (3d Cir. 1995).

11. Upon balancing the factors, the Motion To Amend and Motion To Compel are denied. The first factor weighs heavily in favor of Mylan and Apotex. Silbersher's proposed modification of the ANDA DCO will without question violate the privacy interests of Mylan and Apotex in their "proprietary business information" and, despite Silbersher's assurances, would provide their "competitors an unfair advantage in the marketplace" if their Sealed Documents were disclosed. *Everest Nat'l Ins. Co. v. Sutton*, No. 07-00722, 2010 WL 4387522, at *6, *7 (D.N.J. Oct. 28, 2010) (denying the defendant's motion to amend a confidentiality order in one case in order to be permitted to produce the plaintiff's sealed documents in a second case wherein the plaintiff was not a party).

12. The second factor weighs in favor of Mylan and Apotex. Although Silbersher does not appear to be acting with improper intent, Mylan and Apotex have legitimate reasons to not reveal their business procedures without further assurances that Silbersher will be able to keep them confidential. The third factor weighs in favor of Mylan and Apotex, because "while disclosure would not necessarily cause [them] 'embarrassment' *per se*, it would certainly harm [their] competitive position in the marketplace" if their proprietary information were to be revealed. *Id.* at *6. The fourth factor favors Mylan and Apotex. The Qui Tam Case may concern issues that have impacted public finances due to the additional outlays by government health programs to pay for Zytiga, but the case does not raise issues concerning public health and safety. Silbersher has not alleged that anyone covered by government health programs who needed a prescription for Zytiga following a prostate-cancer diagnosis was denied coverage due to its expense or the lack of a generic alternative.

13. The fifth factor weighs slightly in favor of Apotex and Mylan. Efficiency in the Qui Tam Case would be served if Silbersher were to have immediate access to the Sealed Documents, but whether such unfettered access would be fair to Apotex and Mylan is questionable. Although Silbersher posits that he "has sought the ANDA Litigation documents from [Janssen] in the first instance to minimize the burden on third parties" (ECF No. 221 p. 7 n.3), Mylan and Apotex do not agree that Silbersher is promoting fairness. Silbersher also asserts that if he "had sought the generic companies' ANDA Litigation documents directly via subpoenas (thus increasing the discovery burden on third parties), Mylan and Apotex would have been obligated to produce those same documents directly, without any recourse to the prior DCO in the ANDA Litigation." (ECF No. 222 pp. 6,7.) That argument is conclusory at best, and is likely inaccurate.

14. None of the ANDA Case parties were public entities or officials, and thus the sixth factor is neutral. The seventh factor weighs in Silbersher's favor, in that any *qui tam* case may arguably involve issues that are important to the public. However, in that regard, I find Silbersher's supporting reasoning to be

borderline speculative. (*See* ECF No. 221 p.8 ("The glaring question, which Mylan conveniently ignores, is whether final ANDA approval on October 31 — a mere two days after the expiration of the 30-month automatic stay under the Hatch Waxman regulations on October 29 — is just a coincidence, or instead evidence that [Janssen's] misconduct delayed Mylan's market entry.").) Surely, Mylan and Apotex would express their concerns if they believed that the FDA delayed the approval of their applications to produce abiraterone acetate tablets due to some form of direct nefarious conduct by Janssen.

15. The eighth factor weighs heavily in favor of Mylan and Apotex, in that they have argued repeatedly that they relied upon the sanctity of the ANDA DCO when litigating the ANDA Case. *Everest Nat'l Ins. Co.*, 2010 WL 4387522, at *6 (noting that the party objecting to production of confidential documents in one case to parties in another case "relied on the Discovery Confidentiality Order when it produced" the documents in issue); *Liberty-Lincoln-Mercury, Inc. v. Ford Motor Co.*, No. 02-04146, 2005 WL 8175077, at *2 (D.N.J. May 31, 2005) (denying motion to modify a discovery order to permit the disclosure of the defendant's trade secrets by the plaintiff to nonparties, as those secrets were "akin to a trade secret in a patent case," and the defendant "relied on the confidentiality orders before producing its materials").

16. I am concerned about the resultant chilling effect on ANDA litigation in the District of New Jersey if Apotex and Mylan's reliance on the ANDA DCO were to be ignored, and if the Motion To Amend and Motion To Compel were to be granted. The fact that Silbersher "is not looking for the wholesale public disclosure" of the Sealed Documents produced by Mylan and Apotex in the ANDA Case is of no moment. *Everest Nat'l Ins. Co.*, 2010 WL 4387522, at *8. If Silbersher still seeks production of the Sealed Documents, "the most efficient means to resolve the dispute as to which documents … [Silbersher] should be permitted to obtain is for … [Silbersher] to seek to obtain … [Mylan and Apotex's] documents directly from … [them], the part[ies] with the actual interest in the underlying documents." *Id.* at *7.

17. Silbersher's reliance on *In re Restasis Antitrust Litig.*, No. 18-02819, ECF No. 177 (E.D.N.Y. Nov. 14, 2018), is misplaced. (ECF No. 222 p.5.) That case concerned a *qui tam* claim brought against the brand-name manufacturer of a dry-eye medication. The brand-name manufacturer and the plaintiff-relator jointly served subpoenas upon three generic-manufacturer applicants concerning their confidential communications with the FDA. The brand-name manufacturer and the three generic manufacturers had previously been involved in ANDA litigation in another court. The New York court denied the generic manufacturers' motion to quash the subpoenas. However, that case is distinguishable from our Qui Tam Case for three reasons. First, the brand-

name manufacturer was involved in serving the subpoenas, whereas Janssen is not involved with Silbersher's efforts to seek production of the Sealed Documents. Second, the parties in the *Restasis* case served subpoenas directly upon the generic manufacturers, thereby setting the stage for more in-depth briefing by all those involved, rather than attempting to compel the brand-name manufacturer to produce the documents. Third, the *Restasis* holding lacks any analysis whatsoever that approximates the factors set forth by the Third Circuit in *Pansy* and its progeny.

18. As Mylan and Apotex correctly argue, casting aside the ANDA DCO from the ANDA Case due to Silbersher's needs as the relator in the Qui Tam Case will chill the willingness of generic manufacturers to enter into discovery confidentiality orders in future ANDA litigation. (ECF No. 218 p.4.) Silbersher has already reached agreements with certain generic manufacturers other than Apotex and Mylan to allow Janssen to produce certain Sealed Documents that are covered by the ANDA DCO. (ECF No. 198-1 p.6.) Perhaps Silbersher should continue to meet and confer with those generic manufacturers that are not willingly waiving their rights under the ANDA DCO, and then move for relief against them directly if those discussions do not result in a satisfactory resolution.

Accordingly,

IT IS on this **28th** day of **November 2022** **ORDERED** that:

1. The Motion To Compel and Motion To Amend are **DENIED** to the extent that they concern the Sealed Documents produced by Mylan and Apotex in the ANDA Case.

2. The Motion To Compel and Motion To Amend are **DENIED** as moot to the extent that they concern generic manufacturers other than Mylan and Apotex.

3. The Clerk is directed to terminate ECF No. 198 and ECF No. 199.

/s/ Edward S. Kiel
EDWARD S. KIEL
UNITED STATES MAGISTRATE JUDGE